

## CLAIMS:

1. A process for the induction of immunoglobulin A (IgA) in a mammal which process comprises:
  - 5 (a) actively immunising a pregnant mammal with an antigen by any two routes of administration selected from intramammary (IMM), intraperitoneal (IP) and intramuscular (IM); and
  - (b) actively immunising said mammal with an antigen by a third administration route selected from intramammary (IMM), intraperitoneal (IP) and intramuscular (IM); with the proviso that all three administration routes are different.
- 10 2. A process according to claim 1 wherein in step (a) the two routes of administration selected are IP and IM and in step (b) the third route of administration is IMM.
- 15 3. A process according to claim 1 or claim 2 wherein the two active immunisations of step (a) are effected sequentially, discontinuously or concurrently.
- 20 4. A process according to claim 3 wherein the two active immunisations of step (a) are effected concurrently.
5. A process according to any one of claims 1 to 4 wherein steps (a) and (b) are effected sequentially, discontinuously or concurrently.
- 25 6. A process according to any one of claims 1 to 5 wherein steps (a) and (b) are repeated once or twice prior to parturition.
7. A process according to any one of claims 1 to 5 wherein step (a) is repeated twice, prior to parturition.
- 30 8. A process according to claim 7 wherein each step (a) is effected at 2 to 8 week intervals.
9. A process according to claim 8 wherein each step (a) is effected at 2 to 4 week intervals.
- 35 10. A process according to any one of claims 6 to 9 wherein step (a) is effected 6 to 14 weeks prior to parturition, first repeat step (a) at 2 to 10 weeks prior to parturition,

and the final step (a) at 1 to 4 weeks prior to parturition.

11. A process according to claim 10 wherein step (a) is effected 8 to 12 weeks prior to parturition, first repeat step (a) at 4 to 8 weeks prior to parturition, and the final step (a) at 1 to 4 weeks prior to parturition.
12. A process according to claim 11 wherein step (a) is effected 8 weeks prior to parturition, first repeat step (a) at 4 weeks prior to parturition, and the final step (a) at 1 week prior to parturition.
13. A process according to any one of claims 6 to 12 wherein step (b) is repeated once prior to parturition.
14. A process according to any one of claims 6 to 13 wherein the (b) steps are effected at 1 to 6 week intervals.
15. A process according to claim 14 wherein the (b) steps are effected at 2 week intervals.
16. A process according to claim 13 or claim 14 wherein step (b) is effected 3 to 12 weeks prior to parturition, and repeat step (b) at 1 to 10 weeks prior to parturition.
17. A process according to claim 16 wherein step (b) is effected 4 to 8 weeks prior to parturition and repeat step (b) 2 to 4 weeks prior to parturition.
18. A process according to claim 17 wherein step (b) is effected 4 weeks prior to parturition and repeat step (b) at 2 weeks prior to parturition.
19. A process for the production of mammalian milk containing immunoglobulin A (IgA), which process comprises:
  - (a) induction of IgA according to the process of any one of claims 1 to 18; and
  - (b) collecting milk containing IgA from said mammal.
20. A process according to any one of claims 1 to 19 wherein the antigen comprises at least one of the group of bacteria, yeasts, viruses, mycoplasmas, proteins, haptens, animal tissue extracts, plant tissue extracts, spermatozoa, fungi, pollens,

dust and a complex of antigens.

21. A process according to claim 20 wherein the antigen is a bacterial antigen.
- 5 22. A process according to claim 21 wherein the bacterial antigen is selected from the group consisting of Escherichia, Staphylococcus, Streptococcus, Salmonella, Pneumococcus, Helicobacter, Cryptosporidiosus, Campylobacter and Shigella.
23. A process according to claim 22 wherein the bacterial antigen is *E.coli*.
- 10 24. A process according to claim 20 wherein the antigen is a yeast antigen.
25. A process according to claim 24 wherein the yeast is *Candida albicans*.
- 15 26. A process according to claim 20 wherein the antigen is a protein antigen.
27. A process according to claim 26 wherein the protein antigen is tumour necrosis factor.
- 20 28. A process according to claim 20 wherein the antigen is a complex of antigens.
29. A process according to claim 28 wherein the complex of antigens comprises *E. coli*, rotavirus and coronavirus.
- 25 30. A process according to any one of claims 1 to 29 wherein the antigen is formulated as a suspension.
31. A process according to any one of claims 1 to 30 wherein the antigen is administered together with an acceptable carrier, diluent, buffer, and/or adjuvant.
- 30 32. A process according to claim 31 wherein the antigen is administered together with an adjuvant.
- 35 33. A process according to claim 32 wherein the adjuvant is selected from Freund's complete adjuvant (FCA), Freund's incomplete adjuvant (FIC) adjuvant 65, cholera toxin B subunit, alhydrogel; or *bordetella pertussis*, muramyl dipeptide, cytokinins and saponin. Oil based adjuvants and in particular FCA and FIC are preferred

34. A process according to claim 33 wherein the adjuvant is Freund's incomplete adjuvant.
- 5 35. A process according to any one of claims 1 to 34 wherein the antigen is administered together with an antibiotic.
36. A process according to any one of claims 1 to 35 wherein the antigen administered in each immunising process, and at each site, is the same or different.
- 10 37. A process according to claim 36 wherein the antigen administered in each immunising process, and at each site, is the same.
38. The process according to any one of claims 1 to 37 wherein the mammal immunised is selected from the group consisting of cows, goats and sheep.
- 15 39. A process according to claim 38 wherein the mammal is a dairy cow.
40. IgA produced in accordance with the process of any one of claims 1 to 39.
- 20 41. A process for the production of mammalian milk containing IgA, which process comprises:  
(a) induction of IgA according to the process of any one of claims 1 to 39; and  
(b) collecting milk containing said IgA from said mammal.
- 25 42. IgA containing mammalian milk produced in accordance with the process of claim 41.
43. IgA isolated from the mammalian milk of claim 42.
- 30 44. The IgA of claim 43 which is purified IgA.
45. Use of the IgA of claim 40 or claim 44 as, or in the preparation of, pharmaceutical, cosmetic, and/or veterinary compositions.
- 35 46. Use of the IgA of any one of claims 42 to 44 as, or in the preparation of, food products and/or dietary supplements.

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